DIA training course on

Paediatric Investigation Plans (PIP)

Course #15552
17-18 September 2015
Holiday Inn London Kensington Forum, UK

OVERVIEW

Overview of the Paediatric Investigation Plan (PIP) procedure, including in-depth discussion of specific scientific/regulatory issues in relation to PIPs, case-studies and instructor-led group work on specific cases.

This course will provide a full introduction to PIPs and the EU Paediatric Regulation. The course faculty are European-based leading experts from EMA and industry. Topics will be presented through interactive lectures and hands-on workshop training.

WHO WILL ATTEND

Professionals in regulatory affairs, clinical research, project management, toxicology, product development.

Participants should preferably have a fair understanding of aspects of paediatric medicines development.

Level: Beginner/Intermediate

LEARNING OBJECTIVES

At the conclusion of this course, participants should be able to:

- Describe the EU paediatric regulation
- Discuss the PIP approval procedure
- Identify the expectations and requirements from the Paediatric Committee (PDCO)
- Demonstrate how to prepare a PIP eligible for evaluation by PDCO
- Explain the modification of an agreed PIP procedure
- Describe the compliance check procedure
- Demonstrate an overview of procedures after initial PIP approval

Participants will complete a knowledge check at the end of the course and will be provided with feedback to ensure learning objectives are attained.

KEY TOPICS

- EU paediatric regulation
- PIP lifecycle
- How to get your PIP approved
- PIPs after approval

FACULTY

Mette Due Theilade Thomsen
(Course Director)
Principal Scientist
Novo Nordisk A/S, Denmark

Janina Karres
Paediatric Coordinator, Human Medicines Special Areas/Paediatric Medicines
European Medicines Agency, EU

CONTINUING EDUCATION

DIA meetings and training courses are generally approved by the Commission for Professional Development (CPD) of the Swiss Association of Pharmaceutical Professionals (SwAPP) and the Swiss Society of Pharmaceutical Medicine (SGPM) and will be honoured with credits for pharmaceutical medicine. All participants are eligible for these credits.

ABOUT DIA

DIA is a neutral, global, professional, member-driven association of nearly 18,000 professionals involved in the discovery, development, and life cycle management of pharmaceuticals, biotechnology, medical devices and related health care products.

Through our international educational offerings and myriad networking opportunities, DIA provides a global forum for knowledge exchange that fosters the innovation of products, technologies and services to improve health and well being worldwide. Headquarters are in Horsham, Pa., USA, with offices in Basel, Switzerland, Tokyo, Japan, Mumbai, India and Beijing, China.

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PharmaTrain MASTERING MEDICINES DEVELOPMENT

This course has limited capacity
Register early

DAY 1

08:00 REGISTRATION

09:00 SESSION 1

INTRODUCTION AND DEFINITIONS
- EU paediatric regulation
- PIPs, waivers, deferrals, PDCO
- Guidelines and EMA website

11:00 REFRESHMENT BREAK

11:30 SESSION 2

THE PIP LIFECYCLE: PART 1
Introduction: Preparation, submission, amending PIP after Day 60, opinion
- How to build your PIP and/or waiver request
- Conditions/indications
- How to answer the PDCO Request for Modification at Day 60
- Company Interactions with PDCO
- Global Paediatric Plan

13:00 LUNCH

14:00 SESSION 2 CONTINUED

THE PIP LIFECYCLE: PART 1
Group work
- How to ensure a global paediatric plan
- Definition of conditions/indications

15:00 SESSION 3

THE PIP OPINION
- Key binding elements
- Best practice for synopsis/outline

15:45 REFRESHMENT BREAK

16:15 SESSION 4

THE PIP LIFECYCLE: PART 2
PIPs after approval:
- Modifications
- Changing the scope of the PIP ("Merging & splitting")
- MAA Validation and compliance check

17:30 DRINKS RECEPTION

18:30 END OF DAY ONE

DAY 2

08:30 SESSION 4 (CONTINUED)

THE PIP LIFECYCLE: PART 2
- Annual deferral reports
- Rewards – Supplementary protection certificate (SPC) extension

08:55 GROUP WORK

HOW TO MINIMISE THE NUMBER OF MODIFICATION OF YOUR PIP

09:40 SESSION 5

SPECIAL ISSUES
- Paediatric pharmaceutical forms and formulations

10:00 REFRESHMENT BREAK

10:30 SESSION 5 (CONTINUED)

SPECIAL ISSUES
- Non-clinical studies to support paediatric development
- Paediatric Clinical Studies-Challenges and Solutions

11:30 SESSION 6

WORKSHOP ON CASE STUDIES: PART 1

13:00 LUNCH

14:00 SESSION 7

WORKSHOP ON CASE STUDIES: PART 2

15:30 REFRESHMENT BREAK

16:00 SESSION 8

COURSE SUMMARY

16:30 END OF THE TRAINING COURSE

Training Course Venue

Holiday Inn London Kensington Forum
97 Cromwell Road
London, SW7 4DN
Tel: +44 871 942 9094
www.hikensingtonforumhotel.co.uk

DIA has blocked a limited number of hotel rooms for the course participants from 16 to 19 September 2015 at the rate of GBP 168.00 per single room per night including Full English Breakfast, taxes and service fee. In order to book a hotel room, please call the hotel directly and quote the booking reference "P9M". The room rate is available until 5 August 2015 or until the room block is sold-out, whichever comes first. Cancellations received after 5 August 2015 will be subject to cancellation fee of 100% of the booking value.

- See more at: http://www.diaglobal.org/en/course-listing/training/2015/09/paediatric-investigation-plans-pip/hotel-information#showcontent

REGISTRATION FORM

DIA Training Course on Paediatric Investigation Plans (PIP) | ID#15552

17-18 September 2015 | Holiday Inn London Kensington Forum, UK

DIA DEVELOP INNOVATE ADVANCE

REGISTRATION FEES

Registration fee includes refreshments breaks, lunches and course material. Please check:

FEES	MEMBER	NON-MEMBER
INDUSTRY	€ 1'420.00 ❑	€ 1'580.00 ❑
ACADEMIA/CHARITABLE/GOVERNMENT/NON-PROFIT (FULL-TIME)	€ 710.00 ❑	€ 870.00 ❑
Join DIA now to qualify for the member rate	€ 155.00 ❑	

If DIA cannot verify your membership upon receipt of registration form, you will be charged the non-member fee.

DIA MEMBERSHIP

Join DIA now to qualify to save on future events and to receive all the benefits of membership. Visit **www.DIAglobal.org** and click on Membership for more details.

Payment is due 30 days after registration and must be paid in full by commencement of the course.

The DIA Europe, Middle East & Africa Contact Centre Team will be pleased to assist you with your registration from Monday to Friday between 08:00 and 17:00 CET. Tel. :+41 61 225 51 51 Fax: +41 61 225 51 52
Email: EMEA@DIAglobal.org Mail: DIA EMEA, Küchengasse 16, 4051 Basel, Switzerland Web: www.DIAglobal.org

Cancellation Policy

All cancellations must be made in writing and be received at the DIA Europe, Middle East and Africa office four weeks prior to the event start date. Cancellations are subject to an administrative fee:

- Industry (Member/Non-member) € 200.00
- Academia/Charitable/Government/Non-profit (Full-time) (Member/Non-member) € 100.00

If you do not cancel four weeks prior to the event start date and do not attend, you will be responsible for the full registration fee.

DIA reserves the right to alter the venue and dates if necessary. If an event is cancelled or postponed, DIA is not responsible for airfare, hotel or other costs incurred by registered attendees. Registered attendees are responsible for cancelling their own hotel and travel reservations.

Transfer Policy

You may transfer your registration to a colleague prior to the start of the event but membership is not transferable. Substitute attendees will be responsible for the non-member fee, if applicable. Please notify the DIA office of any such substitutions as soon as possible.

Photography Policy

By attending the event, you give permission for images of you, captured during the conference through video, photo, and/or digital camera, to be used by DIA in promotional materials, publications, and website and waive any and all rights including but not limited to compensation or ownership.

ATTENDEE DETAILS

Please complete in block capital letters or attach the attendee's business card here.

❑ Prof ❑ Dr ❑ Ms ❑ Mr

Last Name

First Name

Job Title

Company

Address

Postal Code

City

Country

Telephone Number Fax Number

email (Required for confirmation)

PAYMENT METHODS

Credit cards: Payments by VISA, Mastercard or AMEX can be made by completing the details below. Please note that other types of credit card cannot be accepted.

❑ **Please charge my** ❑ VISA ❑ MC ❑ AMEX

Card N°

Exp. Date /

Cardholder's Name

❑ **Bank transfers:** When DIA completes your registration, an email will be sent to the address on the registration form with instructions on how to complete the bank transfer. Payments in EURO should be addressed to "Account Holder: DIA." Please include your name, company, Course ID # 15552 as well as the invoice number to ensure correct allocation of your payment.

Payments must be net of all charges and bank charges must be borne by the payer. **If you have not received your confirmation within five working days, please contact DIA Europe, Middle East and Africa.**

By signing below, I confirm that I agree with DIA's Terms and Conditions of booking. These are available from the office or online by clicking **here**.

Date	Signature